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EXAMINER	
BURGESS, JOSEPH D	

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/829,547	ESLER ET AL.	
	Examiner	Art Unit	
	JOSEPH BURGESS	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 11-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 11-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to an amendment filed on 06/10/2009. Claims 1, 18, 30, 33, and 35-37 have been amended. Claims 6-10 have been cancelled. Claims 46-49 have been added. Therefore, claims 1-5 and 11-49 are currently pending and have been examined.

Response to Amendment

2. Applicant's cancellation of claims 6-10 and amendment to claim 33 is sufficient to overcome the 35 USC § 112, first paragraph rejections set forth in the previous office action. Applicant's amendments to claims 1, 18, 33, and 37 and statement on the record regarding the means for language in claim 40 is sufficient to overcome the 35 USC § 112, second paragraph rejections set forth in the previous office action. Applicant's amendment to claims 30-35 is sufficient to overcome the 35 USC § 101 rejection set forth in the previous office action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 5, 11, 12, 14-18, 22, 23, 30, 34, 36, 39, 41, and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaemmerer (US 5,693,076 A).

5. **Claim 1:**

Kaemmerer, as shown, discloses the following limitations:

- *receiving, at a computing device from a caregiver of the patient who is using the computing device, a data message alert including at least in part narrative data supplied by the caregiver of the patient* (see at least column 4, line 49 – column 5, line 25);
- *storing the data message alert on the medical device* (see at least column 4, line 49 – column 5, line 25);
- *interrogating the medical device with a computing device* (see at least column 4, line 49 – column 5, line 25);
- *upon interrogating the medical device, communicating via the computing device, the data message alert stored within a memory of the medical device wherein the data message alert originates from outside the medical device* (see at least column 4, line 49 – column 5, line 25).

6. Claim 2:

Furthermore, Kaemmerer discloses the limitation of *detecting whether the data message alert is stored within the memory of the medical device wherein the data message alert is communicated in response to detecting the data message alert stored within the memory of the medical device* (see at least column 5, lines 1-25).

7. Claim 4:

Furthermore, Kaemmerer, as shown, discloses the following limitations:

- *receiving a new data message alert* (see at least column 4, line 49 – column 5, line 25);
- *in response to receiving the new data message alert, saving the new data message alert to the memory as the data message alert* (see at least column 4, line 49 – column 5, line 25).

8. Claim 5:

Furthermore, Kaemmerer, as shown, discloses the following limitations:

- *receiving a revised data message alert* (see at least column 10, line 60 – column 11, line 13, i.e. physician makes additions or updates to narrative regarding the patient's medication regimen);
- *in response to receiving the revised data message alert, saving the revised data message alert to the memory as the data message alert* (see at least column 11, lines 1-13).

9. Claim 11:

Furthermore, Kaemmerer discloses the limitation of *the memory of the medical device comprises a random access memory (RAM)* (see at least figure 2).

10. Claim 12:

Furthermore, Kaemmerer, as shown, discloses the following limitations:

- *requesting the data message alert* (see at least column 5, lines 1-38);
- *in response to requesting the data message alert, interrogating the medical device* (see at least column 5, lines 1-38).

11. Claim 14:

Furthermore, Kaemmerer discloses the limitation of *in response to detecting the data message alert stored, uploading the data message alert to a database* (see at least column 5, lines 1-38 and column 11, lines 14-33, i.e. programmer interrogates IMD and detects stored data and the data is uploaded into programmer's memory).

12. Claim 15:

Furthermore, Kaemmerer discloses the limitation of *communicating the data message alert in at least one of a variety of data formats compatible for storage in the memory* (see at least column 4, line 49 – column 5, line 25, i.e. communicating and storing a narrative data message in the memory of the implanted medical device as a bit string).

13. **Claim 16:**

Furthermore, Kaemmerer discloses the limitation of *at least one of the data message alert and the variety of data formats compatible for storage in the memory include at least one of the following data formats: ASCII text; multi-media; audio; audio encoding schema; XML; and XML schema definition* (see at least figure 7 and column 10, lines 35-45).

14. **Claim 17:**

Furthermore, Kaemmerer discloses the limitation of *communicating the data message alert comprises at least one of the following: displaying a text pop-up window containing a text message alert via a display device of the computing device; displaying and playing a pop-up multi-media message alert via the display device and an audio output device of the computing device; playing an audio message alert via the audio output device of the computing device; and displaying a text pop-up window containing an XML text string message alert via the display device of the computing device* (see at least figure 4, i.e. text message pop-up window displayed on screen of programmer).

15. **Claim 18:**

Furthermore, Kaemmerer discloses the limitation of *receiving a new data message alert comprises at least one of the following: receiving text of the new data message alert via a first input device of the computing device; receiving a multi-media recording of the new data message alert via a second input device of the computing device; receiving an audio recording of the new data message alert via one of the second input device and a third input device of the computing device; and receiving an XML text string of the new data message alert via one of the first input device and the second input device of the computing device* (see at least column 8, lines 5-21).

16. Claim 22:

Furthermore, Kaemmerer discloses the limitation of *the data message alert comprises at least one of patient-specific information and medical device-specific information* (see at least column 5, lines 13-38).

17. Claim 23:

Furthermore, Kaemmerer discloses the limitation of *wherein the data message alert comprises at least one of the following: a message communicating that at least one of the medical device and a patient utilizing the medical device are enrolled in a clinical study; a message communicating a drug regime for the patient utilizing the medical device; a message communicating information concerning a component of the medical device; and a message communicating a reminder to send in a product registration for the medical device* (see at least column 10, lines 60-67, i.e. physician enters textual narrative about patient's medication regime).

18. Claim 30:

Kaemmerer, as shown, discloses the following limitations:

- *receive, at a computer from a caregiver of the patient who is using the computer, a data message alert including at least in part narrative data supplied by the caregiver of the patient* (see at least column 4, line 49 – column 5, line 25);
- *store the data message alert on the medical device* (see at least column 4, line 49 – column 5, line 25);
- *interrogate the medical device* (see at least column 4, line 49 – column 5, line 25);
- *upon interrogating the medical device, communicate a data message alert stored in a memory of the medical device to the computer* (see at least column 4, line 49 – column 5, line 25).

19. Claim 34:

Furthermore, Kaemmerer discloses the limitation of *the computer readable code for causing the computer to communicate the data message alert includes computer readable code for causing the computer to communicate the data message alert in at least one of a variety of data formats compatible for storage in the memory* (see at least column 4, line 49 – column 5, line 25, i.e. communicating and storing a narrative data message in the memory of the implanted medical device as a bit string) *wherein at least one of the data message alert and the variety of data formats compatible for storage in the memory include at least one of the following data formats: ASCII text; multi-media; audio; audio encoding schema; XML; and XML schema definition* (see at least figure 7 and column 10, lines 35-45).

20. Claim 36:

Kaemmerer, as shown, discloses the following limitations:

- *a programmer, a medical device, and a link between the programmer and the medical device* (see at least column 4, line 49 – column 5, line 25);
- *the programmer operative to receive a data message alert including at least in part narrative data provided by a caretaker of the patient and communicate the data message alert to the medical device for storage* (see at least column 4, line 49 – column 5, line 25);
- *the medical device operative to store the data message alert in a memory of the medical device* (see at least column 4, line 49 – column 5, line 25);
- *the programmer operative to interrogate the medical device and upon interrogating the medical device, communicate the data message alert, wherein the data message alert originates from outside the medical device* (see at least column 4, line 49 – column 5, line 25).

21. Claim 39:

Furthermore, Kaemmerer discloses the limitation of *the link between the programmer and the medical device comprises a radio frequency (RF) signal* (see at least column 6, lines 53-65).

22. Claim 41:

Furthermore, Kaemmerer discloses the limitation of *the programmer includes at least one of a display, a printer, and an audio output device* (see at least figure 4 and column 8, lines 21-27) *and wherein upon interrogating the medical device, the programmer communicates the data message alert as at least one of the following: a pop-up window containing an ASCII text message displayed on the display; a pop-up window containing a multi-media message displayed on the display and played via the audio output device; an audio message played via the audio output device; a pop-up window containing an XML text string message displayed on the display; and a printed text message printed as a header on any printout generated by the programmer until the data message alert is no longer stored in the memory of the medical device* (see at least figure 4, i.e. text message pop-up window displayed on screen of programmer).

23. Claims 47, 48, and 49:

Kaemmerer discloses the limitations as shown in the rejections above. With regard to the limitations of *the data message alert comprises a message communicating that at least one of the medical device and a patient utilizing the medical device are enrolled in a clinical study, the data message alert comprises a message communicating a drug regime for the patient utilizing the medical device,* and *the data message alert comprises a message communicating a reminder to send in a product registration for the medical device,* these limitations are drawn to non-functional descriptive material and are not functionally involved with the method. The recited method steps would be performed the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack,* 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry,* 32 F.3d 1579, 32

USPQ2d 1031 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). See also MPEP 2106.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claims 3, 13, 19, 31, 32, 37, 38, 40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaemmerer (US 5,693,076 A) in view of Levine, et al. (US 6,327,501 B1).

26. Claim 3:

Furthermore, Kaemmerer discloses the limitation of *the data message alert is stored within the memory of the medical device* (see at least column 4, line 49 – column 5, line 25).

Kaemmerer does not explicitly disclose the limitation of *data stored in a dedicated alert field within the memory of the medical device.* However, in at least column 8, lines 13-38, Levine discloses storing data in dedicated fields of the memory of an implantable medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "...storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is

investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

27. Claim 13:

The combination of Kaemmerer/Levine discloses the limitations as shown in the rejections above. Furthermore, Kaemmerer, as shown, discloses the following limitation:

- *establishing communication with the medical device* (see at least column 4, line 49 – column 5, line 25);

Kaemmerer does not explicitly disclose the following limitation, but Levine as shown does:

- *reading the dedicated alert field* (see at least column 8, lines 13-24, i.e. programmer reads dedicated fields).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

28. Claim 19:

The combination of Kaemmerer/Levine discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *detecting whether a data message alert is stored in the memory comprises detecting whether the dedicated alert field is null* (see at least column 13, lines 16-24 and figure 4, i.e. programmer searches for a safety alert data match in a particular dedicated field and if data match is not found in that dedicated field programmer moves to next dedicated field to detect data). It would have been obvious to one of ordinary skill in the art at the

time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

29. Claim 31:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the limitation of *computer readable program code for causing the computer to detect whether the data message alert is stored in a dedicated alert field within the memory of the medical device wherein the data message alert is communicated in response to detecting the data message alert stored in the dedicated alert field*. However, in at least column 12, lines 9-24, Levine discloses that a programmer detects alert information corresponding to a dedicated field and extracts that information from the implantable medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

30. Claim 32:

The combination of Kaemmerer/Levine discloses the limitations as shown in the rejections above. Furthermore, Kaemmerer, as shown, discloses the following limitations:

- *receive the data message alert* (see at least column 4, line 49 – column 5, line 25);
- in response to receiving the data message alert, save the data message alert to the medical device (see at least column 4, line 49 – column 5, line 25).

Kaemmerer does not explicitly disclose the limitation of *dedicated alert field.* However, in at least column 8, lines 13-38, Levine discloses storing data in dedicated fields of the memory of an implantable medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

31. Claim 37:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the limitation of *the memory includes a free form data field having the capability to store the data message alert in a data format and wherein the programmer is further operative to communicate the data message alert in the data format in which the data message alert is stored.* However, in at least column 5, lines 3-27, Levine disclose that a medical device can store analog and digital data and in at least column 9, lines 5-42, Levine also discloses that a programmer memory stores and communicates safety alert data in any format available including text. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a

corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

32. Claim 38:

The combination of Kaemmerer/Levine discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *the free form data field comprises a dedicated alert field* (see at least column 7, line 62 – column 8, line 38, i.e. dedicated fields are included in medical device memory) *and wherein the programmer is further operative to detect whether the data message alert is stored in the dedicated alert field* (see at least column 8, lines 52-61, i.e. dedicated memory field in medical device is flagged when safety alert data is associated with it) *and in response to detecting the data message alert stored, communicate the data message alert* (see at least column 9, lines 43-55, patient complication alert recognized in memory is communicated to medical practitioner). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

33. Claim 40:

The combination of Kaemmerer/Levine discloses the limitations as shown in the rejections above. Furthermore, Kaemmerer discloses the limitation of *the programmer includes means for inputting the data message alert* (see at least column 8, lines 5-21)

Kaemmerer does not explicitly disclose the following limitations, but Levine as shown does:

- *the programmer is further operative to:*
    i. *receive the data message alert prior to detecting the data message alert stored* (see at least column 7, lines 9-35);
    ii. *in response to receiving the data message alert, save the data message alert to the dedicated alert field* (see at least column 8, lines 13-38).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "...storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device..." (Levine, column 8, lines 44-51).

34. Claim 42:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the limitation of *the programmer is further operative to persistently communicate the data message alert until the data message alert is acknowledged.* However, in at least column 13, line 63 – column 14, line 16, Levine discloses that once safety alert information is recognized by programmer it notifies medical practitioner by message on display or printout and insures medical practitioner is aware of the safety alert information. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "...storing patient information and complications in the memory of the implantable medical device and providing a corresponding

data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device..." (Levine, column 8, lines 44-51).

35. Claim 43:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the following limitations, but Levine as shown does:

- *upload at least one of the data message alert, associated patient data, and associated medical device data to the database in response to communicating the data message alert stored in the memory* (see at least column 3, lines 3-31);
- *in response to uploading, provide verification that at least one of the data message alert, the associated patient data, and the associated medical device data is uploaded to an associated storage location within the database* (see at least column 5, line 52 - column 6, line 31, i.e. programmer is connected to separate database which is used to store safety alert information and this is verified during communications with implanted medical device).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "...storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device..." (Levine, column 8, lines 44-51).

36. Claims 20, 28, 29, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaemmerer (US 5,693,076 A) in view of Linberg, et al (US 6,497,655 B1).

37. Claim 20:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the following limitations, but Linberg as shown does:

- *receiving an acknowledgement of the data message alert communicated* (see at least column 16, line 29 – column 17, line 25, i.e. IMD communicates an alert to chronic monitoring module (CMM) regarding a prevailing medical condition and CMM acknowledges receipt of alert by evaluating the need for the alert);
- *in response to receiving the acknowledgement, terminating communication of the data message alert* (see at least column 16, line 29 – column 17, line 25, i.e. IMD terminates session with CMM once CMM evaluates what type of medical condition alert is being sent).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the acknowledgement and termination of communication procedure of Linberg because it, "…provides significant advantages over the prior art by enabling remote troubleshooting, maintenance, and software upgrade to the IMDs…" (Linberg, column 9, lines 45-47).

38. Claim 28:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the following limitations, but Linberg as shown does:

- *interrogating the medical device with at least one wireless device in response to the medical device being within a communications range of the at least one wireless device* (see at least column 11, lines 13-22, i.e. a programmer placed a few feet away from IMD and patient would still be within range to wirelessly communicate with IMD);

- *upon interrogating the medical device with the wireless device, uploading the data message alert to a remote storage location via the wireless device* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD and then programmer uploads data to data center).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the wireless communication and data storage system of Linberg because it, "…is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand…" (Linberg, column 12, lines 16-20)

39. Claim 29:

The combination of Kaemmerer/Linberg discloses the limitations as shown in the rejections above. Furthermore, Linberg discloses the limitation of *interrogating the medical device with the wireless device comprises periodically establishing communication with the medical device and reading at least a portion of the memory* (see at least column 12, line 21 – column 13, line 15, i.e. programmer periodically reads memory of IMD wirelessly when it is a few meters away) *and wherein uploading the data message alert comprises transmitting the data message alert over a network to at least one of a remote database and the computing device* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD and then programmer uploads data to data center). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the wireless communication and data storage system of Linberg because it, "…is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand…" (Linberg, column 12, lines 16-20)

40. Claim 44:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the following limitations, but Linberg as shown does:

- *interrogate the medical device in response to the medical device being within a communications range of the wireless device therein detecting whether the data message alert is stored in the memory* (see at least column 11, lines 13-22, i.e. a programmer placed a few feet away from IMD and patient would still be within range to wirelessly communicate with IMD and detect data in IMD memory);
- *in response to detecting the data message alert stored in the memory, upload at least one of the data message alert, associated patient data, and associated medical device data to the database* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD and then programmer uploads data to data center).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the wireless communication and data storage system of Linberg because it, "...is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand..." (Linberg, column 12, lines 16-20)

41. Claim 45:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the following limitations, but Linberg as shown does:

- *interrogate the medical device in response to the medical device being within a communications range of the wireless device* (see at least column 11, lines 13-22, i.e. a programmer placed a few feet away from IMD and patient would still be within range to wirelessly communicate with IMD);

- *upon interrogating the medical device, upload the data message alert to the programmer via the networked link* (see at least column 11, lines 13-35, i.e. data is communicated wirelessly to programmer from IMD).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the wireless communication and data storage system of Linberg because it, "…is designed to be broadband capable of simultaneously supporting multiple information sets and architecture, transmitting at relatively high speed, to provide data, sound and video services on demand…" (Linberg, column 12, lines 16-20)

42. Claims 21, 25-27, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaemmerer (US 5,693,076 A) in view of Levine, et al. (US 6,327,501 B1) in further view of Mann, et al. (US 5,833,623 A).

43. **Claim 21:**

The combination of Kaemmerer/Levine discloses the limitations as shown in the rejections above. The combination of Kaemmerer/Levine does not explicitly disclose the following limitations, but Mann as shown does:

- *receiving a request to clear the data message alert from the dedicated alert field* (see at least column 8, lines 31-44);
- *in response to receiving the request to clear, clearing the data message alert from the dedicated alert field whereby the dedicated alert field is rendered null* (see at least column 8, lines 31-44).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the ability to clear the memory of a medical device of Mann because it, "…permits the subsequent capture of new diagnostic data…" (Mann, column 8, lines 35-36).

44. Claim 25:

The combination of Kaemmerer/Levine discloses the limitations as shown in the rejections above. Furthermore, Levine discloses the limitation of *in response to detecting that the dedicated alert field is not null, including the data message alert in any reports generated by the programmer* (see at least column 13, line 63 - column 14, line 16, i.e. programmer can notify medical practitioner of safety alert information by generating a report on the display or through a printout). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

The combination of Kaemmerer/Levine does not explicitly disclose the limitation of *until the dedicated alert field is rendered null.* However, in at least column 8, lines 31-44, Mann discloses clearing data from the memory of the implantable medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the ability to clear the memory of a medical device of Mann because it, "…permits the subsequent capture of new diagnostic data…" (Mann, column 8, lines 35-36).

45. Claim 26:

The combination of Kaemmerer/Levine/Mann discloses the limitations as shown in the rejections above. Furthermore, Kaemmerer discloses the limitation of *the data message alert comprises a*

text message alert (see at least column 4, line 49 – column 5, line 25) *and wherein including the data message alert in the any reports generated by the programmer comprises printing the text message alert in any printouts generated by the programmer* (see at least column 18, lines 9-19).

46. Claim 27:

The combination of Kaemmerer/Levine/Mann discloses the limitations as shown in the rejections above. Furthermore, Kaemmerer discloses the limitation of *the text message alert is printed as header text of the any printouts generated by the programmer* (see at least column 18, lines 9-19).

47. Claim 33:

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the limitation of *computer readable code for causing the computer to initialize the medical device prior to interrogating the medical device.* However, in at least column 10, lines 36-55, Levine discloses that a medical device is implanted by medical practitioner and initiated by control program of programmer. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with implantable medical device data storage method of Levine because, "…storing patient information and complications in the memory of the implantable medical device and providing a corresponding data structure in the external programmer enables the new medical practitioner to be advised of the particular complications and special circumstances at the time the new medical practitioner is investigating the performance of the implantable medical device…" (Levine, column 8, lines 44-51).

The combination of Kaemmerer/Levine does not explicitly disclose the limitation of *the computer readable code for initializing the medical device includes computer readable code for causing the computer to clear the memory of any data message alerts.* However, in at least column 8, lines

31-44, Mann discloses clearing data from the memory of the implantable medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the ability to clear the memory of a medical device of Mann because it, "…permits the subsequent capture of new diagnostic data…" (Mann, column 8, lines 35-36).

48. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaemmerer (US 5,693,076 A) in view of Haller, et al. (US 7,181,505 B2).

49. **Claim 24:**

Furthermore, Kaemmerer, as shown, discloses the following limitations:

- *uploading at least one of patient data and medical device data to the database* (see at least column 11, lines 14-33).
- *utilizing the data message alert* (see at least column 5, lines 13-38)

Kaemmerer does not explicitly disclose the following limitation, but Haller as shown does:

- *verify that at least one of the patient data and the medical device data are being uploaded to a correct study registry in the database for the clinical study* (see at least column 36, lines 20-34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the clinical study implantable medical device data acquisition method of Haller because, "…patient, clinical study and overall health care costs are reduced, while the rate at which such studies may be completed, and the scope, amount and types of clinical data which may be acquired using such methods, are increased…" (Haller, column 38, lines 57-61)

50. Claims 35 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaemmerer (US 5,693,076 A) in view of Greeninger, et al. (US 6,082,367 A).

51. **Claim 35:**

Kaemmerer, as shown, discloses the following limitations:

- *receive a data message alert via a programmer* (see at least column 4, line 49 – column 5, line 25);
- *in response to receiving the data message alert, saving the data message alert to a memory of the medical device* (see at least column 4, line 49 – column 5, line 25);
- *upon interrogating the medical device, communicating the data message alert via the programmer wherein the data message alert originates from outside the medical device* (see at least column 4, line 49 – column 5, line 25).

Kaemmerer does not explicitly disclose the following limitations, but Greeninger as shown does:

- *the data message alert including at least in part a user-recorded audio message provided by a caregiver of the patient* (see at least column 24, lines 13-22, i.e. physician can store voiced statement in IMD),
- *playing the user-recorded audio message* (see at least column 23, lines 21-36),

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the method of storing and playing implantable medical device audio messages of Greeninger because, "…the capability of recording voiced statements…allows a more flexible, less error prone and safer audible feedback and control…" (Greeninger, column 6, lines 54-57)

52. **Claim 46:**

Kaemmerer discloses the limitations as shown in the rejections above. Kaemmerer does not explicitly disclose the limitation of *at least one of the data message alert and the variety of data formats compatible for storage in the memory includes audio.* However, in at least column 4, line

37 – column 5, line 31, Greeninger discloses audio or voiced messages can be stored in the memory of the IMD. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the implantable medical device narrative data storage technique of Kaemmerer with the method of storing and playing implantable medical device audio messages of Greeninger because, "…the capability of recording voiced statements…allows a more flexible, less error prone and safer audible feedback and control…" (Greeninger, column 6, lines 54-57)

Response to Arguments

53. Applicant's arguments regarding the 35 USC § 103 rejections of claims 1-5, 11-14, 16-20, and 22-45 as set forth in the previous Office Action have been considered but are moot in view of the new grounds of rejection. Also, it is unclear why applicant is arguing the rejection of claim 7 as it was cancelled.

54. With regards to claim 24 and applicant's argument that Haller fails to disclose that the patient and/or the medical device are enrolled in a clinical study and that the data message alert is used to verify that the patient data and/or the medical device data are being uploaded to a correct study registry in the database for the clinical study, the Examiner respectfully disagrees. First of all, Haller discloses that patients consent to release medical information and their IMDs are interrogated for data used in clinical studies (column 38, lines 25-61). This would mean that they would have to be enrolled in a clinical study to consent to release their personal and IMD data to a clinical study. Additionally, Haller discloses that an IMD would store a code, which is a form of data message, and that receipt of such a code could be employed as a precondition to receiving information from remote system (column 36, lines 20-34) which could be a remote health care provider initiating communication for clinical study monitoring (column 35, lines 54-60). This code is employed at a remote system or elsewhere to verify the identity of the patient or the type of model of IMD (column 36, lines 20-34). Obviously this code would verify the patient or medical device data are being uploaded to the study registry requesting the data.

55. Additionally, with regard to claims 15 and 21, applicant did not properly traverse Examiner's taking of Official Notice. As the response is inadequate to rebut the Examiner's taking of Official Notice, the noticed facts are hereinafter deemed admitted prior art. The Examiner would like to note the requirements for traversing Official Notice from MPEP § 2144.03:

> To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard, 139 F.2d at 713, 60 USPQ at 241* ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be inadequate. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also *Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697* ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2). If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate. (MPEP § 2144.03(C))

To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

If applicant does not traverse the examiner's assertion of Official Notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office Action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant

either failed to traverse the examiner's assertion of Official Notice or that the traverse was inadequate [emphasis added].

Because Applicant has not specifically pointed out any errors in the Examiner's action, the Officially Noticed facts in the 03/13/2009 Office Action are deemed admitted prior art. However, in the interest of advancing prosecution, Examiner has provided prior art citations in the new grounds of rejection that show the obviousness of the claimed matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **JOSEPH BURGESS** whose telephone number is **(571)270-5547.** The Examiner can normally be reached on Monday-Friday, 9:00am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **CHRISTOPHER GILLIGAN** can be reached at **(571)272-6770**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **(866)217-9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to **571-273-8300**. Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

Randolph Building

401 Dulany Street

Alexandria, VA 22314.

JOSEPH BURGESS

8/19/2009

Examiner

Art Unit 3626

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626